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ALLIANCE HEALTHCARE PARTNERS LLC

UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

SURGICAL INSTRUMENT SERVICE COMPANY, INC.,

Plaintiff/
Counterclaim-Defendant

vs.

INTUITIVE SURGICAL, INC.,

Defendant/
Counterclaim-Plaintiff.

Lead Case No. 3:21-CV-03496-VC
Hon. Vince Chhabria
Dept. 5

DECLARATION OF JEFFREY L. BERHOLD IN RESPONSE TO DEFENDANT INTUITIVE SURGICAL, INC.'S MOTION TO CONSIDER WHETHER ANOTHER PARTY'S MATERIAL SHOULD BE SEALED PURSUANT TO CIVIL LOCAL RULE 79-5(f)

I, Jeffrey L. Berhold, declare as follows:

1. I am over the age of eighteen years old and am counsel for non-party Alliance Healthcare Partners LLC ("Alliance"). Unless otherwise indicated, I state the following of my own personal knowledge and, if called upon to do so, I could and would testify competently to the following.

2. Pursuant to Civil Local Rules 7-11 and 79-5(f), Alliance submits this declaration in response to defendant Intuitive Surgical, Inc.'s ("Intuitive") Administrative Motion to Consider Whether Another Party's Material Should Be Sealed. Alliance seeks to maintain the confidentiality of AHP000527 from its 510(k) application for repairing EndoWrists and requests that the Court seal the document itself and redact quotations from it and references to it.

3. Alliance filed a 510(k) application with the FDA (K210478) on behalf of non-party Restore Robotics Repairs LLC ("Restore"). The 510(k) application concerns the development, testing, and regulation of proposed methods for repairing EndoWrists. The application was submitted with the understanding based on FDA regulations that the agency would only disclose the 510(k) summary – and only disclose the public summary after clearance. *See* 21 C.F.R. § 20.61(c). The courts of this district and circuit have routinely sealed 510(k) applications because the information in such documents is valuable and its disclosure to competitors would be extremely damaging. *See*, *e.g.*, *Edwards Lifesciences Corp. v. Meril Life Scis. PVT. Ltd.*, No. 19-CV-06593-HSG, 2020 WL 6118533, at *11 (N.D. Cal. Oct. 16, 2020), *Lucas v. Breg, Inc.*, No. 15-cv-00258-BASNLS, 2016 WL 5464549, at *2 (S.D. Cal. Sept. 28, 2016) (sealing 510(k) premarket submission to the FDA addressing safety and effectiveness of device).

4. Alliance produced the 510(k) application, including correspondence with the FDA, for Attorney's Eyes Only under a subpoena and protective order in *Restore Robotics, LLC v. Intuitive Surgical, Inc.* (N.D. Fla. 19-cv-55). Alliance later consented to its production by Intuitive in this matter under a similar

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protective order. Since production in this matter, the FDA has cleared K210478 and published the 510(k) summary. After clearance, Alliance conveyed the 510(k) clearance to Restore through the sale of the 510(k) applicant Iconocare Health Solutions. Earlier this year, Restore resolved its dispute with Intuitive.

5. Consistent with industry practice, Alliance and Restore have always maintained the 510(k) file within a closely held group of individuals on a need-to-know basis within the companies. Disclosure would give substantial assistance to potential competitors – allowing them to avoid potentially years of time and millions of dollars required to develop their own production and testing methods and regulatory strategy.

6. Intuitive has provided notice that it has provisionally filed an eleven-page letter from the FDA to Alliance regarding K210478 (AHP000527) under seal with several motions to exclude testimony of expert witnesses. I represented Alliance and Restore in *Restore Robotics v. Intuitive Surgical* and represent Alliance and Restore regarding the confidentiality of AHP000527. Neither Alliance nor Restore has disclosed AHP000527 to any third party because it would allow competitors to make use of Alliance and Restore's extensive efforts to commercialize repaired EndoWrists. The letter is part of a dialogue between the applicant and the agency regarding the development, testing, and regulation of proposed methods for repairing EndoWrists. Disclosure would provide competitors with a significant head start in their own efforts.

7. Moreover, it would bring significant risk of confusion to the public because the correspondence is far from the final word on the production, testing, and marketing eventually cleared in the application on September 30, 2022. *See*, *e.g.*, *Sarafin v. BioMimetic Therapeutics, Inc.*, No. 3:11-0653, 2013 WL 139521, at *18 (M.D. Tenn. Jan. 10, 2013) ("What is clear, however, is that a deficiency letter is not a final FDA decision, but a request for more information, and, in fact, 'very few' PMA are approved without the issuance of a deficiency letter."). In fact, the

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FDA has cleared the application and published the 510(k) summary, which governs the clearance.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed: March 29, 2023

Jeffrey L. Berhold

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